RESPONSE TO FINDING
IR-00-001-01-FIN

Summary of Finding

During performance of an inspection of the Design Process conducted January 10-14, 2000 at the Contractor's offices, the Regulatory Unit (RU) identified the following:

1. Section 5.3.2, "Instructions and Procedures", of the Quality Assurance Program and Implementation Plan (QAPIP) requires processes that affect quality to be conducted using approved instructions and procedures.

a. Procedure K70P003_0, "Design Review", November 1998, states under the Section titled "Activity," that the Design Manager/Functional Lead ensures that a Design Control Checklist (DCCL) is completed for design presented for review.

Contrary to the above, as of January 14, 2000, DCCLs were not used in design reviews conducted from May 1999 through January 14, 2000, based on interviews with Contractor staff, review of design review meeting minutes, and records in Project Document Control.

b. Procedure K70P003_0, "Design Review", dated November 1998, states under the section titled "Activity" that the actions from the review are progressed through routine project control meetings and completion is recorded with the review record. The Section titled "Records", states that documentation generated by this procedure shall be submitted to Project Document Control.

Contrary to the above, during the inspection, the inspectors found that not all actions were being statused, many open actions were no longer applicable based on major design changes, and not all action closures were being documented in Project Document Control.

c. Procedure K13P053_1, "Quality Assurance Surveillance", dated August 1999, Milestone 1, requires QA staff to prepare and the Project QA Manager to approve, a surveillance schedule.

Contrary to the above, during the inspection, the inspectors were informed that no approved surveillance schedule had been issued.

d. Procedure K13P053_1 required in Appendix 2, that personnel performing surveillance activities are to plan the surveillance and prepare checklists or requirement documents for use during the surveillance.

Contrary to the above, checklists or requirements documents were not prepared for the three surveillance activities documented in the following surveillance reports: SV-W375-99-QA00018, "Surveillance of Design Change Control Process", Rev. 0, dated September 7, 1999; SV-W375-99-QA00020, "Surveillance of Design Change Control Process", Rev. 0, dated November 29, 1999; and SV-W375-99-QA00024, "Surveillance of Engineering Calculations", Rev. 0, dated December 14, 1999.

The four examples of failure to follow procedures, as described above, are considered a Finding.

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL Inc. agrees with the Finding.

2. Reason for the Finding

a. Initial issue of the procedure, Design Review, K70P003, incorrectly included the use of a form, a Design Control Check List (DCCL) for single discipline review. The personnel conducting single discipline review meetings recognized the error and did not use the DCCL. While a procedure revision that included the elimination of the DCCL was circulated for general review in early June 1999, it has not yet been issued.

   The reasons for the finding are: 1) the failure to issue a Procedure Change Request (PCR) to eliminate the DCCL requirement when the problem was initially identified instead of waiting for the less timely procedure revision process to incorporate the necessary change in concert with other changes, and 2) lack of specific awareness of the need to comply with the procedural requirements until they are changed.

b. The Design Review process, under the leadership of Engineering Management, was used to comply with periodic contract design review requirements. This finding occurred because K70P003, Design Review, was not revised by a PCR to reflect a shift in responsibilities from the Design Managers and Design Leads to Engineering Management for the conduct of the review activities. As a result, responsibility for action item tracking and closeout, and documentation transmittal to Project Document Control (PDC) was unclear. Consequently, the Functional Discipline Managers who were leading the single discipline reviews, were not clear on their procedural responsibility to track actions and document action closures through PDC. A contributing cause was the frequency and magnitude of design changes experienced in this design confirmation phase such that many actions became irrelevant as the design evolved.

c. Procedural noncompliance. A surveillance schedule had been prepared and approved but had not been brought to the attention of the inspectors. This schedule, however, had not been maintained current as additions and deletions were made.

d. The Quality Assurance Program and Implementation Plan (QAPIP) states in section 10.2.1 that checklists or redlined procedures are prepared to guide the performance of surveillances. However, project procedure K13P053, Quality Assurance Surveillance, does not clearly specify the requirement to prepare checklists or red lined procedures for the surveillance activity. Although marked procedures were used for the surveillances, they were not maintained as part of the record following issuance of the surveillance report. The surveillance reports do detail document sections reviewed in the surveillances as required by the procedure.

3. Corrective steps that have been taken and the results achieved

The following remedial actions have been taken or will be taken:

a. A Procedure Change Request to K70P003 that eliminates the unintended use of the DCCL for single discipline reviews has been issued effective March 1, 2000. Meanwhile, a more extensive revision to procedure K70P003 is in process that will more fully describe the design review process and the intended function of the DCCL as the requirements list that identifies those key documents (and revisions) that are to be periodically sent by Design Leads to the cognizant Functional Discipline Managers for review and comment. The training requirements have been reviewed and updated for the affected personnel and this should assure adequate awareness and implementation of the revised requirements. This procedure revision is scheduled for issue by April 30, 2000. This was a unique occurrence since there is no other procedure requiring use of the unique DCCL form.

b. The anticipated revision of K70P003 includes very specific and explicit statements as to the responsibilities of Design Managers and of Design Leads to status actions and document closeout of actions through PDC. This revision also consolidates the relevant content from the associated Code of Practice to eliminate some inconsistencies. The requirements and responsibilities will be clarified. The Functional Engineering Manager has counseled those Functional Discipline Managers responsible for tracking and reporting action item closures from past reviews to complete their activities and document closures through PDC before April 2000. Reviews conducted in May 2000 and beyond (i.e., after the issuance of the procedure revision) will be conducted under the revised Design Review procedure.

c. A project assessment schedule was updated by the quality assurance staff and approved by the Acting Project Quality Assurance Manager on February 15, 2000.

d. No remedial actions are required. The areas surveilled in the referenced surveillances have been documented in the surveillance reports.

4. The corrective steps that will be taken to avoid further Findings

a. The current project emphasis on strict procedural compliance, the near-term procedure revision which has clear direction as to how the DCCL is to be used, and the recent revision of the engineering training requirements will be coupled with effective Engineering Department self-assessments and periodic Quality Assurance (QA) surveillances to ensure no recurrence of the identified non-compliance. The absolute need for procedural compliance was emphasized by the Project Manager to all RPP-WTP personnel at a series of meetings conducted on March 2, 2000.

b. Similar to a) above, the project's cultural emphasis on procedural compliance, the issuance of the revised procedure which clearly states the responsibilities and requirements for action item statusing and closeout, including transmittals to PDC, and the recent training program clarifications, supported by periodic Engineering Department self-assessments and QA surveillances should assure no recurrence of the identified non-compliance.

c. Visibility of this activity within the quality assurance organization has been raised due to this finding. The project assessment schedule will be prepared and approved annually, updated periodically (estimated on a quarterly basis), and maintained continuously.

d. The Code of Practice for TWRS Privatization Quality Assurance Audit and Assessment Personnel Qualification, K13C053, will be revised to include the detailed requirement to document the areas surveilled or to maintain checklists or redlined requirements documents as part of the surveillance file.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

a. The Procedure Change Request eliminating the DCCL requirement in K70P003, Design Review, has been issued effective March 1, 2000 and no variance with the authorization basis exists.

b. The outstanding open action closure activities for past Design Reviews conducted by the Functional Engineering organization will be completed by June 30, 2000.

c. The project is in full compliance with the applicable commitments in the authorization basis with regard to this finding.

d. K13C053 will be revised and training provided to QA personnel conducting surveillances by April 30, 2000.

RESPONSE TO FINDING
IR-00-001-02-FIN

Summary of Finding

During performance of an inspection of the Design Process conducted January 10-14, 2000 at the Contractor's offices, the Regulatory Unit (RU) identified the following:

2. Section 3.13, "Reliability, Availability, Maintainability, and Inspectability (RAMI)", of the Contractor's Integrated Safety Management Plan (BNFL-5193-ISP-01, Rev. 4, dated December 2, 1998), requires that testability and inspectability of Safety Design Class systems and components be facilitated during design by such features as redundancy, that allow for a system or component to be removed from service for maintenance or testing without loss of safety protection and provisions, and inspection for preventative maintenance or assessment of conditions.

Contrary to the above, the Contractor had neither proceduralized nor implemented the requirement to consider the inspectability and testability into the ongoing Integrated Safety Management process in support of the evolving facility design.

This is considered an inspection Finding.

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL Inc. agrees with the Finding in that BNFL has not implemented the requirement to consider inspectability and testability into the ongoing Integrated Safety Management Process. BNFL disagrees with the Finding that the requirement to consider inspectability and testability was not proceduralized. The requirement to consider inspection and testing is included in the Design Guide for Integrated Safety Management Cycles I and II, K70DG528. The requirement is included in both the version dated September 7, 1999 and the current version dated October 22, 1999. However, this information was not brought to the attention of the RU at the time of the inspection.

2. Reason for the Finding

The requirement to consider inspection and testing is given in the Integrated Safety Management Plan (ISMP). However, the extent to which this requirement should be implemented is not presented in the ISMP as a process that depends on the stage of the design. At the time of the inspection, the level of design detail was such that little consideration of inspection and testing was possible. The ISM team's interpretation of the ISMP requirement was that inspection and testing must be considered when the design is sufficiently mature. The inspector's interpretation was that the requirements must be met at an interim point in the process.

With respect to the proceduralization of the requirements, a more appropriate location is K70C514, Code of Practice for Development of Hazard Control Strategies and Identification of Standards. The

guidance for exactly how and when the testability and inspectability should be incorporated will be retained in the design guide.

3. Corrective steps that have been taken and the results achieved

The current Design Guide for Integrated Safety Management Cycles I and II, K70DG528A, (dated October 22, 1999) for implementation of the ISM process addresses the requirement to consider inspection and testing of Safety Design Class (SDC) systems, structures, and components (SSCs). The design guide lists the information that must be considered when identifying requirements for SSCs. Section 2.2.5, Standards Identification, Step 2 (Identification of SSC Requirements) includes:

- testing/calibration requirements
- inservice inspection requirements.

These requirements are being considered in ISM Cycle 2 reviews to the degree permitted by available design detail.

Enhancement of the proceduralization of these requirements through a change to K70C514 will reinforce K70DG528. The entry in K70C514 will clarify the time phase relationship of reliability, availability, maintainability, and inspectability (RAMI) with design maturity.

4. The corrective steps that will be taken to avoid further Findings

The ISMP will shortly undergo a planned revision. It is intended that the revised ISMP will contain more information on the timing of implementation of all of the requirements contained in the ISMP. This explanation is intended to describe the iterative development process leading to full compliance with some ISMP requirements where they cannot be met immediately.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

Revision of K70C514 will be completed by March 31, 2000.

Compliance with the requirements of the authorization basis will be achieved progressively as the design is evolved. The requirements for inspection and testing will be fully defined when the design is complete. K70DG528, Design Guide for Integrated Safety Management Cycles I and II, describes the mechanics of implementing this requirement. The Hazards Analysis Report (HAR) and Construction Authorization Request (CAR) submissions will document that these requirements have been met. Documentation of testing and inspection requirements at a level consistent with the stage of design development, will be completed by April 30, 2000.

RESPONSE TO FINDING
IR-00-001-03-FIN

Summary of Finding

During performance of an inspection of the Design Process conducted January 10-14, 2000 at the Contractor's offices, the Regulatory Unit (RU) identified the following:

3. Section 6.2.2 and 6.3 of the QAPIP requires that the Quality Assurance (QA), review selected design documents and design review activities to ensure that appropriate quality requirements and criteria were adequately addressed.

Contrary to the above, the QA design document oversight program was not fulfilling the QAPIP requirement in that it did not include an adequate review of design documents and design review activities. For example, the QA organization was not reviewing engineering documents and activities, such as drawings, design review efforts, ISM (Integrated Safety Management) reviews, design input/output verification activities, DIM (Design Input Memorandum) development, and SIPD (Standards Identification Process Database) development.

This is considered an inspection Finding.

BNFL Inc. response:

1. Agreement or disagreement with the Finding

BNFL agrees with the Finding.

2. Reason for the Finding

Documentation of Quality Assurance (QA) document review activities either by the completion of a Document Review Request or by the completion of a surveillance report for the review of in-process activities was insufficient to provide adequate evidence of activities completed. The review of selected design documents and activities was also impaired by the lack of adequate resources.

3. Corrective steps that have been taken and the results achieved

Steps that have been taken or will be taken include: documentation of reviews of the selected design documents and activities by Document Review Request form completion, signature of QA on document approval, and by the completion of a surveillance report for the review of in-process drawing and specification review activities, design review activities, and any other scheduled or ad hoc surveillances performed on selected design activities.

Some examples of these activities include:

- Drawings: Selected drawings have been reviewed and documented as surveillance activities.

- Design review meetings: Quality Assurance Engineers have been attending Area Design Managers meetings since October 1999.
- Integrated Safety Management Process: 14 documents, procedures, Authorization Basis Amendment Requests, etc. have been reviewed.
- Design input/output verification activities: All authorization basis documents have been reviewed. 40 calculations in project document control as of December 1999 were reviewed. Surveillances were performed on 8 Design Change Notices and 40 Design Change Authorizations in Project Document Control in November 1999 and January 2000.
- Design Input Memorandum (DIM): 37 DIMs have been reviewed since March 7, 2000. No DIMs were issued prior to March 7, 2000.
- Engineering procedures: 35 engineering procedures have been reviewed.
- Technical specifications: 8 technical specifications have been reviewed.

These independent assessments include performance of technical and QA audits, inspections, and surveillances. Design process elements such as those listed in the finding are assessed for compliance with requirements and procedures through the surveillance process as defined in procedure K13P053, Quality Assurance Surveillance. From a technical perspective, product quality is further ensured through the design review activities as defined in procedure K70P003, Design Review. The QA organization also is a reviewer of a significant amount of design document and activity outputs as required by Sections 4 and 7 of the Quality Assurance Program and Implementation Plan (QAPIP).

4. The corrective steps that will be taken to avoid further Findings

These activities will be completed to avoid further findings.

- Programmatic implementation of the surveillance program. In progress.
- Documentation of ongoing design document and design activities by either a Document Review Request and Document Review Record or by the completion of a surveillance report for those ad hoc activities reviewed by surveillances
- Revision of the Code of Practice for QA Document Review, K13C050, to clarify the requirement to clearly document the selected reviews conducted
- Based on resources allocated, ensure surveillance schedules are implemented to address selected design activities to provide adequate assurance that the QA requirements for design and engineering activities in design are being adequately implemented.

As part of the recent initiative to improve overall project quality performance, BNFL has committed to implementing a series of action plans. One plan, Corrective Action Management, includes actions to ensure that audit, surveillance, and corrective action and management feedback systems are sufficiently effective to ensure project processes are performing their intended functions.

5. The date when full compliance with the applicable commitments in the authorization basis will be achieved

The surveillance schedule will be issued by April 30, 2000.

K13C050 will be revised by April 30, 2000.

Training will be provided to QA personnel by April 30, 2000.

The action plan, Corrective Action Management, will be implemented by August 1, 2000.

RESPONSE TO FOLLOW-UP ITEM
IR-00-001-04-IFI

Summary of Follow-up Item

Lack of procedures or implementation of QAPIP requirements to define and specify data quality requirements.

Response:

Paragraph 4 of letter 00-RU-0210 requests either a copy of BNFL's response to Deviation and Corrective Action Report (DCAR) WP&DP-AUE-00-01 or a written response describing how BNFL intends to address the data quality issue. BNFL's response to the DCAR does not specifically address data quality issues. The following is BNFL's response to IR-00-001-04-IFI.

The procurement, specification, and verification of external data are governed under the Project Quality Assurance Program and Implementation Plan (QAPIP). The lower tier Quality Assurance Program Description (QAPD) identifies a crosswalk matrix of implementing procedures such as K40P001, Procurement Process, K13C021, Code of Practice for Review and Approval of Documents, and K70P555, Design Verification. Section 7.2.3 of the QAPIP requires that suppliers be evaluated and placed on an Approved Suppliers List as long as the qualification status is maintained. Further, audits of the supplier QAP are conducted based on the complexity and importance of the service in order to assess how effectively their program is being implemented.

A key principle in terms of the adequacy of the data quality is that there are quality programs in place at the subcontractors that have been audited for compliance. The QAPIP requirements are flowed down to subcontractors as our correspondence shows, and as K40P001 requires. Our Research and Technology (R&T) subcontractors are primarily Pacific Northwest National Laboratories (PNNL), Savannah River Technology Center (SRTC) and Vitreous State Laboratory (VSL). Further, all of these laboratories have had critical roles in supporting national programs (e.g., RW-0333P for High Level Waste production) and, as a result, their programs employ recognized national standards. The subcontractors have also been qualified to our quality assurance requirements and are on the Approved Suppliers List.

BNFL specifies in the task specification that the subcontractors must have QA programs that specifically apply to data collection, retention, validity, verification, etc. (as required by procedure K40P001), and thus, BNFL accesses the suite of procedures that address data quality, accuracy, precision, calibration, detection limits, sample integrity, data review/acceptance, data deviations, etc. Additional requirements are documented in a specific "Quality Assurance Project Plan for Testing Programs for SRTC, PNNL, and the VSL" that addresses data quality, quality control, analytical methods, etc. as specified in U.S. Environmental Protection Agency guidance documents. This document is formally transmitted to the laboratory as part of the task order requirements.

Our current subcontractors' procedures identify acceptance and reporting requirements for data. Typically, these meet the recognized standards SW-846, RW-0333P, or NQA-1 depending if the results are intended for Regulatory, High Level Waste, or other purposes. The data (e.g., as test

reports) are received in a controlled manner by our Project Document Control organization per K13P008. R&T distributes the documents for review according to the procedure, K13C021, Code of Practice for Review and Approval of Documents, which utilizes a Document Review Request followed by a Document Review Record. Both R&T and the design organizations (and others) review the data/test reports. DOE-ORP and their subcontractors also participate and provide review comments that are documented.

If the data is intended as a design input, it is identified per the Design Input Memoranda (DIM) process according to procedure K70P557, Design Inputs. Subsequently, the Design Verification process is employed per K70P555, where at least the third independent review is documented. If the data package is not a design input per se but still used, it will invariably be referenced as part of a calculation or system description, which also will be checked in an independent, formal manner. Note that in some cases, the data generation may be planned as "scoping" in nature; for example, where the flow sheet is not firm, such as with sulfate for LAW or permanganate precipitation of Sr/TRU for LAW envelope C solutions.

BNFL intends to revisit the overall process and procedures to ensure that we have addressed the issues raised in the inspection and make our process clearer where needed. BNFL will generate a succinct, overarching strategy that outlines the requirements and processes, and specifically identifies when qualified data will be required. This strategy will be produced in the form of a plan document by June 30, 2000. New or upgraded procedures to execute the strategy will be generated by July 28, 2000. In addition, BNFL will review R&T data generated prior to the formalization of the strategy to assure the data quality is appropriate for the use. This review will be completed by July 28, 2000. BNFL will flow this methodology down to subcontractors.